DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-83

August 6, 1999

Brett J. Phillips, President
Phillips Gulf Corporation
8767 - 115th Avenue
Largo, Florida 33773

Dear Mr. Phillips:

This letter is in reference to your marketing of the product, ARTH-Rx Oral Capsules.

Product labeling, including the immediate container label, the carton container, and the flyer reading in part, "Announcing A Significant Advancement...", include claims which state or suggest that your product is useful in the treatment of osteoarthritis, rheumatoid arthritis and sports injuries.

These claims cause the product to be a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, the drug is a new drug as defined in Section 201(p) of the Act because it is not generally recognized as safe and effective for treating the diseases referenced in the previously mentioned labeling.

The drug is also misbranded since its labeling is false or misleading because it suggests that the product is safe and effective for its intended uses when in fact this has not been established [Section 502(a) of the Act]. The product is further misbranded because its labeling fails to bear adequate directions for those uses stated or suggested in product labeling [Section 502(f)(1) of the Act].

This letter is not intended to be an all inclusive review of all your firm's products or labeling. It is your responsibility to assure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to make prompt corrections may result in enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunctions against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter describing the specific steps you have taken to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

Douglas D. Tolen
Director, Florida District

cc: [redacted]